

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of therapeutic effect of green tea mouthwash and nystatin suspension in denture stomatitis

Protocol summary

Summary

Objectives: In this study the antifungal effect of Green tea mouthwash 0.5% on patients with denture stomatitis was examined. Design: Twenty two patients with denture stomatitis who had been referred to the department of oral medicine in sari faculty of dentistry in spring 1396 were divided into two groups. Setting and conduct: One group received treatment with green tea mouthwash 0.5% four times a day and each time use 15 milliliter about 2.5 table spoon for two weeks. Another group use nystatin suspension 100000 u/l four times a day and each time use 1 milliliter about 20 drops for two weeks. Participants including majoreligibility criteria: Absence of using denture in sleeping; No use of antifungal drugs and antibiotics and corticosteroid in past 1 month; No allergy to nystatin suspension; Absence of immunodeficiency; Absence of alzheimer; Absence of cyhalological disorders; Absence of musculoskeletal disorders; Ability to consume mouthwash. Main outcome messures: First examination is before treatment is run to check the length and the width of lesions.7 days after first examination, in the second examination length and width are written.14 days after first examination, in the third examination length and width are written again.the microbial culture is done before treatment and after 14 days. Finally the data of two groups are compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060334314N1**

Registration date: **2017-07-12, 1396/04/21**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-07-12, 1396/04/21

Registrant information

Name

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Name of organization / entity

Mazandaran university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2017-06-26, 1396/04/05

Expected recruitment end date

2017-07-01, 1396/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of therapeutic effect of green tea mouthwash and nystatin suspension in denture stomatitis

Public title

comparison of therapeutic effect of green tea mouthwash in the treatment of stomatitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Absence of using denture in sleeping;

No use of antifungal drugs and antibiotics and corticosteroid in past 1 month; No allergy to nystatin suspension; Absence of immunodeficiency; Absence of alzheimer; Absence of cyhalological disorders; Absence of musculoskeletal disorders; Ability to consume mouthwash

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 22

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

The number of sampling is chosen by convenient sampling. After that, by random sampling, one group of samples are located in the first intervention group, another group of samples in the second intervention group. Each individual is assigned a number and then randomly chosen so the objectivity of the research is reached.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The ethics committee of Mazandaran University of Medical Sciences

Street address

Vice chancellor for research, Mazandaran university of medical science, The martyr Motahhari square, Street teacher

City

Sari

Postal code

48157-3391

Approval date

2017-04-22, 1396/02/02

Ethics committee reference number

IR.MAZUM.REC.96.2948

Health conditions studied**1****Description of health condition studied**

denture stomatitis

ICD-10 code

B37.0

ICD-10 code description

Candidal stomatitis Oral thrush

Primary outcomes**1****Description**

length and width of lesions

Timepoint

Before intervention, one week after the beginning of intervention, two weeks after the beginning of intervention

Method of measurement

calliper _ cm

2**Description**

colonies number

Timepoint

Before intervention, two weeks after the beginning of intervention

Method of measurement

Number of fungi

Secondary outcomes

empty

Intervention groups**1****Description**

The first intervention group use the green tea mouthwash 0.5% 4 times a day each time 15 milliliter about two and half table spoon. They should use it after washing their mouth and use it for one minute in their mouth. They should refrain from eating and drinking for about one hour. It should be used for two weeks.

Category

Treatment - Drugs

2**Description**

The second intervention group use the nystatin suspension 1000000 u/l four times a day and each time use one milliliter about 20 drops. They should use it after washing their mouth and use it for one minute in their mouth. They should refrain from eating and drinking for about one hour. It should be used for two weeks.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Clinic, Mazandaran University of Medical Sciences

Full name of responsible person

Dr.Anahita Ghorbani

Street address

Dental clinic, Khazar Blvd, Khazar square Sari Mazandaran

City

Sari

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mazandaran University of Medical Sciences

Full name of responsible person

Ahmad Ali Enayati

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Vice chancellor for research, Mazandaran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

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Professor / Associate Professor, School of Dentistry

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty